

### **REMARKS**

In response to the Final Office Action mailed December 18, 2008, Claims 1-15 and 17-27 stand pending and examined. Claims 1, 13, 14 and 27 have been amended. Support for the amendments may be found generally throughout the specification and specifically within paragraphs 26, 29, 40-41, 106, 117, 127, 134, 142 and Figures 1A and 1B inclusive. No new matter has been added.

It is respectfully submitted that the amendments and remarks presented herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §101, §102, §103, or §112. Rather, the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

A three (3) month extension of time is requested. Authorization is given to charge the fee for the extension, as well as any additional fee deemed necessary for consideration of this paper, to Deposit Account No. 08-2525.

#### **Claim Rejections – 35 USC 103**

Claims 1-2, and 7-12 stand rejected under 35 USC 103(a) as being unpatentable over Kalbacher et al. The Examiner bases this rejection upon the number of elution steps, while acknowledging that claims directed to a single elution step would be non-obvious. Applicants respectfully traverse and overcome this rejection.

##### **A. 35 USC 112, 2nd paragraph**

1. Claims 1-15 and 17-27 stand rejected for alleged indefiniteness under 35 USC 112, second paragraph with regard to the term “femtomolar”. The Examiner contends that “femtomolar” does not specify a specific amount/range, notwithstanding the Examiner’s previous acknowledgement of such term being clear and definite. Applicants respectfully traverse and overcome this rejection.

Applicants first note for the record that the term "femtomolar" is described and defined within paragraph 29 of the specification, with a specific detailed range of about 16 to about 320 femtomoles further defined. Claims 1, 13, 14 and 27, as previously amended (see April 9, 2007 response to the January 5, 2007 office action), reflect this defined and definite femtomolar range. As the other claims in this rejection depend upon base claims 1, 13 and 14, Applicants respectfully submit that the term "femtomolar" is described and distinctly defined, with a specific detailed range, in Claims 1-14 and 17-27.

The Examiner has now stated that the 112, 2<sup>nd</sup> paragraph rejection would be obviated by amending claims 1, 13, 14 and 27 to recite the range of "about 16 to 320 femtomoles" and remove the recitations of "femtomolar amount." In order to speed prosecution of this case, Applicants have adopted the Examiner's suggestion to amend Claims 1, 13, 14 and 27 accordingly. Applicants therefore respectfully submit that the 112, 2<sup>nd</sup> paragraph rejection has been obviated and respectfully submit the rejection be withdrawn and said claims be placed into condition for allowance.

**B. 35 USC 103(a)**

1. Claims 1-2, and 7-12 stand rejected under 35 USC 103(a) as allegedly anticipated by Kalbacher et al (J. Chromatography [1991] 548:343-350). The Examiner bases this rejection upon the number of elution steps, while acknowledging that claims directed to a single elution step would be non-obvious. Applicants respectfully traverse and overcome this rejection.

Kalbacher is asserted to teach isolation of antigenic peptides from human HLA-DR MHC class II molecules in femtomolar amounts via elution of a HLA-DR molecule-synthetic influenza peptide matrix after immunoaffinity purification, subsequent ultrafiltration, and then co-incubation with the potential antigenic peptides and subsequent acid elution of the HLA-DR molecules. The Examiner acknowledges that Kalbacher fails to teach concentration of the eluate, but that one of ordinary skill in the

art would be able to elute at a wide range of concentrations. Applicants respectfully traverse.

Applicants note that the method of Kalbacher more specifically allegedly discloses the isolation of HLA-DR molecules which are then contacted with synthetic influenza matrix peptides. The HLA-DR molecules are purified with immunoaffinity and then eluted. Subsequently the buffer and detergent were exchanged by ultrafiltration. The isolated HLA-DR molecules are then co-incubated with potential antigenic peptides and the peptides bounded by the HLA\_DR molecules are then isolated with addition of acid. Therefore Kalbacher requires and teaches a first elution of the HLA-DR molecule-synthetic matrix peptide complex and then, after ultrafiltration and co-incubation, requires and teaches a second elution wherein the potential antigenic peptides are eluted from the molecules via acid.

In contrast, Claim 1 only requires one elution step and additionally comprises a washing step of the sequestered peptide receptor (MHC class II molecule)-antigenic peptide beaded complex (See also paragraphs 106, 117, and 127). Kalbacher does not teach nor disclose this method, but instead teaches away from Applicants claimed invention, as Kalbacher requires two elution steps and does not provide a washing of the beaded peptide receptor-antigenic peptide complex. Furthermore, the Examiner acknowledges that Kalbacher fails to teach concentration of the eluate in both of its elution steps. Finally, Kalbacher provides no motivation nor suggestion for eliminating one elution step and then adding a washing of the beaded peptide receptor-antigenic peptide complex. Accordingly, Applicants respectfully submit that Kalbacher does not anticipate, nor render obvious, Applicants claimed invention.

Applicants therefore respectfully submit that the 103(a) rejection has been overcome and that said rejection as to claims 1-2, 7-12, 14-15, 19, 20 and 23-26, as amended, should be withdrawn and said claims put into condition for allowance.

No further fee is required in connection the filing of this Amendment. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

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